

## **REMARKS**

Claims 7-31, 33-34, 43-46, and 48-49 are pending in this application, with claims 27-31, 33-34, 43-46 and 48-49 being under consideration. In this Amendment, claims 27 and 43 have been amended, and claims 32 and 47 have been cancelled. Support for these amendments may be found, for example, at page 10, lines 4-9, page 11, lines 4-7, and in Examples 1 and 2 of the specification. No new matter is presented herein.

### ***Obviousness-Type Double Patenting Rejection***

Claims 27-34 and 43-49 were provisionally rejected under the doctrine of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-28 of co-pending Application No. 11/271,666. Applicants respectfully request that this rejection be held in abeyance until there is an indication of allowable subject matter in one of these two applications.

### ***The Presently-Claimed Invention***

The presently-claimed invention relates, generally, to a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch, and is coated with at least one antimicrobial agent. The package comprises a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity. The antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article. Further, the packaged elastomeric article is capable of being stored and/or transported for a period of time without significant loss of antimicrobial activity.

The claimed elastomeric articles beneficially minimize or reduce cross-contamination that can occur as a result of contact by a wearer or user of the article with more than one other object. When the antimicrobial agent is applied to the surface in contact with the wearer's hand, the elastomeric articles also inhibit growth of skin flora. See paragraph [0034]. The package system, which includes a moisture-resistant water-vapor impermeable barrier and a desiccant, reduces relative humidity and maintains

said reduced relative humidity in the vicinity of the antimicrobial elastomeric article. See paragraph [0037]-[0038].

***Rejection under 35 U.S.C. § 103(a)***

Claims 27-34 and 43-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman").

Applicants respectfully traverse this rejection.

The Office Action relies upon Modak for allegedly disclosing an antimicrobial elastomeric article (a glove) that includes anti-infective agents such as chlorhexidine salts and quaternary ammonium halides, where the glove may be pretreated with an adsorption site saturating treatment including a quaternary ammonium compound such as didecyldimethylammonium chloride. Additionally, the Office Action asserts that Modak discloses gloves that are essentially free of starch and powder, however, fails to provide a specific citation within Modak of such a teaching. Applicants respectfully submit that the Office Action's characterization of the disclosure of Modak is not correct, especially with respect to a disclosure regarding gloves that are substantially free of starch and powder. In contrast to the Office Action's characterization, Modak relates to an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid which is preferably a modified corn starch. See col. 2, lines 20-22. Although a suitable lubricating agent may include zinc oxide, hydroxycellulose, or corn starch that has been blocked with benzalkonium chloride, didecyldimethylammonium chloride, or gluconic acid, Modak specifically teaches that it is preferably a modified corn starch. See col. 2, lines 20-22 and 51-63. The corn starch must be blocked in order to prevent the anti-infective agent from being adsorbed. The anti-infective agent is provided inside the glove to protect health care workers from exposure to pathogens, such as HIV and HBV. See col. 1, lines 32-40.

McDevitt is cited for disclosing a finger glove that is contained in a package "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." Paragraph [0189]. However, McDevitt does not remedy the deficiencies of Modak with respect to the presently-claimed invention. McDevitt relates to a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. The finger glove may also include an elastic nonwoven material to provide form-fitting properties. The finger glove of McDevitt is intended for use as an applicator or personal cleaning product, such as a swab or oral hygiene device, but there is no disclosure of a packaged elastomeric article that is essentially free of powder and/or starch and is coated with at least one antimicrobial agent.

The Office Action admits that neither Modak nor McDevitt discloses a packaged antimicrobial elastomeric article that includes a desiccant in the package, but takes the position that the use of desiccants in packaging was known in the art at the time the invention was made, and relies upon Shichman (see col. 2, lines 49-51) for disclosing this feature.

However, Shichman merely discloses packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. The articles do not incorporate antimicrobial agents, and there is no disclosure of preserving antimicrobial activity of an elastomeric article that is essentially free of powder and/or starch and is coated with at least one antimicrobial agent by including a desiccant in a package containing an antimicrobial elastomeric article.

The Office Action takes the position that it would have been obvious, given the disclosures of Modak, McDevitt, and Shichman, to provide antimicrobial elastomeric articles in a package containing a desiccant. One skilled in the art would allegedly have been motivated to do so in order to extend the antimicrobial activity of an elastomeric article.

However, Applicants respectfully disagree with this position.

Modak addresses the problem of loss of activity of CHG during storage, which they hypothesize as being caused by uptake of CHG into the glove body and/or other coatings/agents applied to the glove. Modak expressly teaches two ways of addressing this problem (see col. 3, line 50 to col. 4, line 26). The first solution is to apply excess CHG to the glove with the expectation that some will be adsorbed into the glove. The second solution is to apply a thin layer of a nonadsorbent lubricating agent to the surface also bearing the coating of CHG, where the lubricating agent blocks the adsorption of the CHG into the glove material. This thin layer lubricating agent is preferably a silicone emulsion or a polyurethane (see col. 4, lines 19-22), which is either added to the original fluid for molding the glove or applied between the drying and curing steps (see col. 4, lines 27-32). The coating containing CHG is then applied either before or after curing of the glove body. *Id.*

Accordingly, given the solutions Modak specifically discloses for addressing the problem of absorption of CHG into the glove, one skilled in the art would not be motivated to combine those solutions with further packaging and dessicating agents, because the use of additional packaging and dessicating agents would be redundant and/or unnecessary. Although redundancy in design might be good practice in certain fields (e.g., aerospace, transportation safety, communications networks, etc.), the field relating to the antiviral surgical or examination gloves of Modak, which are intended for single use and to be disposable, is not one of them. Indeed, for single use, disposable articles, one skilled in the art would be motivated *to avoid* any redundant or unnecessary features in the design to minimize the cost of the single use, disposable articles. As such, Applicants submit that the Office Action is using impermissible hindsight to find motivation to combine Modak with McDevitt and Schichman to arrive at the presently-claimed invention.

The present application discloses that it is surprising that sufficient CHG activity can be maintained even when low concentrations of the antimicrobial agent are applied to the glove (see specification at page 31, last paragraph). Applicants theorize that use of a packaging structure prevents ambient moisture from accelerating the uptake of

water-soluble antimicrobial agent(s) into the glove body. The Examples in the present specification (particularly Examples 3 and 4) provide comparative data that demonstrate that antimicrobial activity is maintained when the elastomeric article is packaged vs. unpackaged, even when relatively low concentrations of antimicrobial agent(s) are applied to the gloves.

Applicants submit that the combination of Modak, McDevitt, and Shichman does not disclose or suggest the features of independent claims 27 and 43, in which antimicrobial elastomeric articles that are essentially free of powder and/or starch and are coated with at least one antimicrobial agent are provided in a package comprising a desiccant for reducing relative humidity in the vicinity of the elastomeric article, in order to extend the antimicrobial activity of the elastomeric article.

Nothing in the disclosures of Modak, McDevitt, and Shichman would lead one skilled in the art to modify them to arrive at the presently-claimed invention without the benefit of hindsight reconstruction based on Applicants' disclosure. Applicants therefore submit that claims 27-31, 33-34, 43-46 and 48-49 are not unpatentable over the combination of Modak, McDevitt, and Shichman, and respectfully request withdrawal of this rejection.

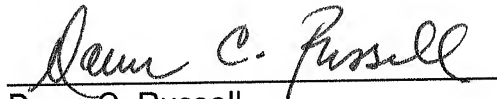
### **CONCLUSION**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 27-31, 33-34, 43-46 and 48-49, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00017**.

Respectfully submitted,

A handwritten signature in cursive script, reading "Dawn C. Russell", is written over a horizontal line.

Dawn C. Russell  
Registration No. 44,751  
Attorney for Applicants

Customer No. 079439  
ARENT FOX LLP  
1050 Connecticut Avenue, N.W., Suite 400  
Washington, D.C. 20036-5339  
Tel: (202) 857-6000  
Fax: (202) 638-4810